K043127

JAN - 4 2005

Section 10: 510(k) Summary

Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter	Haemonetics Corporation 400 Wood Road Braintree, MA. 02184-9114

Company Contact	Gabriel J. Muraca, Jr. RA Project Manager Haemonetics Corporation 355 Wood Rd. Braintree, MA. 02184-9114

Device Name	**Proprietary Name:** Cardiovascular Perioperative Autotransfusion System (cardioPAT™) **Common Name:** Autotransfusion apparatus **Classification Name:** Autotransfusion apparatus (74 CAC)

Predicate Device	The currently marketed predicate device is the Haemonetics® Orthopedic Perioperative Autotransfusion System (OrthoPAT®).

Device Description

The cardioPAT system is designed to provide perioperative autotransfusion for patients undergoing cardiovascular surgery. The system consists of an electromechanical device and a sterile single-use disposable set, which together collect and process red blood cells (RBCs) lost during and after surgery. It is a small portable system which mounts on an IV pole. It is designed to be used in the operating room to recycle blood lost during cardiovascular surgical procedures and in the recovery room to recycle blood lost after surgery, where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour.

Indications for Use

The Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™) is indicated for use to salvage red blood cells from blood lost intraoperatively and postoperatively during cardiovascular surgical procedures, where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour.

Autotransfusion is indicated for patients who meet at least one of the following criteria:

- The patient is expected to lose sufficient blood in the perioperative period, so as to require red blood cell transfusion, and autotransfusion will likely reduce or eliminate the need for allogeneic blood transfusion.
- Religious beliefs cause the patient to refuse allogeneic transfusion, but accept autologous transfusion.
- Compatible allogeneic blood is not available.
- The patient is unable to donate sufficient quantities of autologous blood prior to surgery to adequately cover the anticipated transfusion requirement.
- The patient or physician prefers perioperative autotransfusion rather than preoperative autologous donation or transfusion of allogeneic blood.

Performance

The quality of salvaged red blood cells returned to the donor during autotransfusion procedures with both the current OrthoPAT and modified cardioPAT systems is acceptable with respect to measured markers.

The following table is a summary of Tables 1, 2 and 3 from the test report TP- & TR-DIS-02028, **Exhibit 5**. It shows the mean percent washout and the mean percent red blood cell recovery for pools of different hematocrit blood that were processed under simulated use conditions by the cardioPAT system.

Table 1: Data Summary* for cardioPAT

	Mean Washout			Mean Red Blood Cell Recovery
Hematocrit	Supernate Heparin (%)	Supernate Albumin (%)	Supernate Hemoglobin (%)	(%)
5%	99.88	99.90	99.38	77.83
15%	99.68	99.80	98.18	88.77
40%	97.19	97.67	94.37	91.00
Mean	98.9	99.1	97.3	85.9

*From TP- & TR-DIS-02028

Table 2 compares the combined means of the cardioPAT results from Table 1 and compares them to the combined mean test results previously obtained, using similar pools of blood, which were processed on the predicate OrthoPAT system (Test Report V0007, K962475, provided in **Exhibit 5**).

Table 2: Combined Pool Results Comparison

	Mean Washout			Mean Red Blood Cell Recovery
Data Source	Supernate Heparin (%)	Supernate Albumin (%)	Supernatant Hemoglobin (%)	(%)
OrthoPAT V0007 (SW 3.0c)	98.9	98.9	98.4	83.8
cardioPAT TP-DIS-02028	98.9	99.1	97.3	85.9
% Difference	+ 0.0	+ 0.2	- 1.1	+ 2.1

This comparison shows that there is less than 2% difference in combined mean percent (%) washout values and less than 3% difference between the mean percent red blood cell recovery values. Because these percent differences are very small, they are not considered clinically significant. The cardioPAT system performance test results are within the expected operating efficiencies of the predicate OrthoPAT device, which demonstrates performance equivalence.

Substantial Equivalence

The substantial equivalence of the cardioPAT System is supported by its similarities in intended use, technological characteristics, and performance as compared to the currently marketed OrthoPAT system.

Gabriel J. Muraca, Jr.

Date: November 10, 2004

Gabriel J. Muraca, Jr.
RA Project Manager
Haemonetics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2005

Haemonetics Corporation
c/o Mr. Gabriel J. Muraca, Jr.
RA Project Manager
355 Wood Road
Braintree, MA 02184-9114

Re: K043127
Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™)
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: November 10, 2004
Received: November 12, 2004

Dear Mr. Muraca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043127

Device Name:

Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™)

Indications for Use:

The Haemonetics® Cardiovascular Perioperative Autotransfusion System (cardioPAT™) is indicated for use to salvage red blood cells from blood lost intraoperatively and postoperatively during cardiovascular surgical procedures, where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour.

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Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043127